EXHIBIT 1

GRAY REED

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The Honorable Ron Clark
United States District Court for the Eastern District of Texas
300 Willow Street, Suite 221
Beaumont, Texas 77701

June 17, 2015

Re: Civil Action No. 1:14-cv-00104; *Mark A. Barry, MD. v. Medtronic, Inc.*; In the United States District Court for the Eastern District of Texas, Beaumont Division.

Judge Clark:

Medtronic seeks leave to file a motion for summary judgment that all claims of the patents in suit are invalid under § 102(b), either due to an "on sale" bar or "public use" of all the claimed inventions prior to the patents' priority date of December 20, 2003. Medtronic's invective aside, leave should be denied.

I. Medtronic has not attempted to meet the legal requirements for invalidity under either prong of § 102(b).

Medtronic's argument fails completely because it attacks "the invention," without addressing any particular claims in any patent. "Although Section 102 refers to "the invention" generally, the anticipation inquiry proceeds on a claim-by-claim basis." *Hakim v. Cannon Avent Group PLC*, 479 F.3d 1313, 1319 (Fed. Cir. 1998). Likewise, the on-sale bar portion of § 102(b) is examined a claim-by-claim basis. *Allen Eng'g. Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1353 (Fed. Cir. 2002). Similarly, an anticipatory public use under § 102(b) must exhibit all of the claim limitations. *Star Scientific, Inc. v. RJ Reynolds Tobacco Co.*, 655 F.3d 1364, 1377 (Fed. Cir. 2011); *see also*, *Lough v. Brunswick Corp.,* 86 F.3d 1113, 1122 n. 5, (Fed. Cir. 1996) ("[e]ach claim of the patent must be considered individually when evaluating a public use bar."). Medtronic's request for leave is thus deficient.

A. Mislabeled Figure 6 does not invalidate under § 102(b).

Dr. Barry has stated that Figure 6 in the patents in suit was included by mistake, and that it came from a June 10, 2013 surgery that did not use any claimed invention. Barry Declaration, Ex. A, ¶ 7. Knowing full well this is true, Medtronic nonetheless argues that the label describing Figure 6 as a surgery done with the "present invention" invalidates the patents. It does not.

Indeed, Figure 1 is the completed apparatus, and is labeled as "the present invention." *See* '358 patent, Col 4, lns. 20-25. That figure includes the "Wrench cross

linking members 40," which transverse the spine. Each claim of the '121 patent requires "cross linking members" or their equivalents crossing the spine. Moreover, it is undisputed that the "wrench cross linking member 40" in Figure 1 was invented in the fall of 2004. *See* Slides of July 2004 IMAST presentation (showing apparatus as of that date with no "wrench cross linking member"), Ex. B; Declaration of Bob Pfefferkorn, Ex. C, ¶ 12; Barry Declaration, Ex. A, ¶ 17. Simply taking Dr. Barry's admitted error in using the wrong photo, and its corresponding label, does not change the facts of when the present invention in Figure 1 was developed—i.e., less than one year before the priority date, nor does it address each claim of each patent, as is required in a proper invalidity analysis.

Dr. Barry has explained that the photo in Figure 6 comes from a June 10, 2013 operation that used a system that not only lacked the cross member in Figure 1, but also lacked the linked handles required in every claim of every patent. Barry Declaration, Ex. A, ¶ 6. Dr. Barry has explained the photo was sent mistakenly to his patent lawyer in lieu of the correct photo. Barry Declaration, Ex. A, ¶ 7; Answer to Interrogatory No. 1. Simply put, an error was made, but that does not change the fact that the results of the June 10, 2013 surgery depicted in Figure 6 do not anticipate any claim under § 102(b).

B. The IMAST February 2004 Abstract and July 2004 Presentation do not show any claim invalid under § 102(b).

Medtronic incorrectly argues that a February 2004 abstract is invalidating prior art. The abstract was submitted by Dr. Barry in his application to present to an advanced spine surgical conference ("IMAST"). The abstract is a short summary of the topic, and the full presentation with slides and audio as given in July 2004 is attached. IMAST Presentation, Ex. B.[1] Medtronic ignores the July 2004 presentation slides and voice recording as presented at the conference, which elaborate and expand on the work summarized in the abstract.

The presentation itself is significant in several respects: 1) the voice-over specifically states that the technique evolved over 21 surgeries, refuting any argument that the methods and apparatus were perfected, "ready for patenting," and "reduced to practice" in the context of every claim of every patent, from the first surgery forward; 2) the July presentation shows that follow up of patients after surgery was required to determine if the methods and apparatus as they existed at that point were completed (i.e., "ready for patenting" or "reduced to practice"); 3) because the IMAST presentation was in July 2004, it predates the wrench comb (40) of Figure 1 of each patent, which is in every claim of the '121 patent, and cannot invalidate those claims; 4) the early surgeries, those before summer of 2003, did not include the linked handles found in every claim, and those handles were not completed until follow ups were completed in January 2004. Pfefferkorn Declaration, Ex. C, ¶ 8; Barry Declaration, Ex. A, ¶ 14.

[1] A DVD containing the presentation, with working videos and audio, has been mailed to the Court and opposing counsel. The audio recordings were added about one month after the presentation and reflect Dr. Barry's written speaker notes from the presentation.

The July 2004 IMAST slides refer to an average of one-year follow up with patients prior to the July 2004 presentation, meaning some of the surgeries were more than a year before July 2004 and some less. Any surgery in 2004 is after the critical date. Further, the extensive follow up before the first public presentation of any technique underscores the need for experimentation and testing as the process evolved. The IMAST slides and voice-over corroborate Dr. Barry's amendments to his interrogatory answers because they show an evolution of development, which, even at the time of the presentation, was not complete (e.g., the wrench cross comb 40), as well as the need for follow up to complete testing before any method or apparatus could be disclosed to the public. Notably, the abstract relied upon by Medtronic lacks the detail sufficient to evaluate any claim of any patent and never mentions a wrench comb.

C. Experimental use negates both "ready for patenting" and "public use."

Medtronic bears the burden of proof by clear and convincing evidence to show invalidity under § 102(b). *Microsoft Corp. v. i4i Ltd. P'ship,* 131 S. Ct. 2238, 2242 (2011). Once a §102(b) defense is raised, the patentee had the burden of coming forward with facts about experimental use, even though the ultimate burden of proof remains on the defendant. *TP Laboratories v. Professional Positioners, Inc.*, 724 F. 2d 965, 972 (Fed. Cir.), *cert. denied*, 469 U.S. 826 (1984).

i. The need for testing.

Testing by an inventor in public is not by itself a public use. The seminal case on the experimental-use doctrine involved testing pavement on a road for years. *City of Elizabeth v. Am. Nicholson Pavement Co.*, 97 U.S. 126, 136 (1877). Further, experimental use negates what otherwise would be invalidating public uses. *In re Omeprazole Patent Litigation,* 536 F. 3d 1361, 1375 (Fed. Cir. 2008).

In the context of medical devices, courts have found experimental use is aptly required to determine the safety, efficacy, and repeatability of a procedure or device. *TP Products, supra*. *Ethicon, Inc. v. US Surgical Corp*., 762 F. Supp. 480, 496 (D. Conn. 1991), *aff'd.* 965 F.2d 1065 (Fed. Cir. 1992). Here, for example, Dr. Barry did not have an apparatus that he felt accomplished all of his goals for linking handles until after he had the slotted handles shown in the July 2004 IMAST photo—less than one year before the patents' priority date. He did four surgeries with that apparatus (July 31, August 4, 5, and October 14, 2003). For each of these four surgeries, he followed up with the patient with x-rays at intervals up to one year. The use of linkages was novel in the field and Dr. Barry felt that, at a minimum, he could not be sure he had developed instruments and a technique separate from his own skill that others could reliably and safely use, until having completed at least the three-month follow up on each of those four surgeries (January 2004). *See* Barry Declaration, Ex. A, ¶ 13. This is consistent with *In re Omneprazole*, in which even Phase I and Phase II clinical trials were not sufficient to show safety, and a Phase III trial was required and still considered experimental. The

July 2004 IMAST presentation discusses incremental development and patient follow up, which illustrates the need for both.

ii. Confidentiality as a factor for testing and public use.

Confidentiality is a factor to be considered in "public use," but as shown in *City of Elizabeth* and *MIT*, it is not required. *MIT v. Harman, Int'l. Ind., Inc*., 584 F. Supp. 2d 297 (D. Mass. 2008). The emphasis in the public-use analysis is whether an inventor has turned his invention over to others so that it appears to now be in the public domain. *Moleculon Research Corp. v. CBS, Inc*., 793 F.2d 1261, 1266 (Fed. Cir. 1986) a*brogated on other grounds by Egyptian Goddess, Inc. v. Swisa, Inc.,* 543 F.3d 665 (Fed. Cir. 2008) (en banc) (Display of game by developer to friends was not public use). The fact that an inventor keeps control over his invention and the testing of it is a strong factor cutting against a finding of "public use." *MIT, supra*.

Moreover, confidentiality has been found to be implied in cases where no written non-disclosure agreements exist. In *TP Prod*ucts, the dentist patient relationship was a sufficient basis to infer confidentiality for "experimental use" of a dental retainer, even though the patient could go to any dentist and the device was removable. "In any event, a pledge of confidentiality is indicative of the inventor's continued control which here is established inherently by the dentist-patient relationship of the parties." *TP Products,* 724 F. 2d at 972. This is consistent with the implied duty of confidentiality inferred from circumstances around testing of surgical devices in *Ethicon, Inc. v. US Surgical Corp*., 762 F. Supp. 480, 496 (D. Conn. 1991), *aff'd.*, 965 F.2d 1065 (Fed. Cir. 1992).

Here, there was both express and implied confidentiality. Because all of Dr. Barry's work occurred in operating rooms, as in *TP Products and Ethicon*, there was an implied duty of confidentiality. The medical device sales person, Robert Pfefferkorn, who was present from late 2002 though the spring of 2004 and helped obtain certain instruments, expressly understood the development was confidential, as did other operating room personnel. Pfefferkorn Declaration, Ex. C, ¶ 10; Booher Declaration, Ex. D; Munro Declaration, Ex. E; Y. Barry Declaration, Ex. F. The only other medical doctor who observed the procedures and the use of the apparatus from start to finish was Dr. Barry's ex-wife, who sometimes assisted, and who understood the development was confidential. Y. Barry Declaration, Ex. F. No other orthopedic doctor watched the operation (the anesthesiologist, the only other doctor in the room, was behind a sterile curtain and with his machines some feet away). Barry Declaration, Ex. A, ¶ 20.

iii. Not a public use if the third party is uniformed.

Finally, a use is not an invalidating public use if the disclosure is only to persons who do not have the technical acumen to understand the claimed invention: "when disclosure is limited to a small number of uninformed observers there may be no reason to believe 'that a viewer ... could thereby learn anything of [the later-patented invention]' and disclose the invention to others.… In such cases, a finder of fact might reasonably

conclude that the third party's use remained confidential and that the invention was not 'accessible to the public.'" *DEY, LP v. Sunovion Pharmaceuticals, Inc*., 715 F. 3d 1351, 1356 (Fed. Cir. 2013) (internal citations omitted). In its petitions for *Inter Partes* Review, Medtronic submitted the declaration of Dr. Lawrence Lenke in support of its §§ 102 and 103 positions, and the relevant portion regarding one of skill in the art is quoted in Dr. Barry's attached declaration. Barry Declaration, Ex. A, ¶ 20. Dr. Lenke asserts one of ordinary skill in the art would be either a medical doctor or a medical device designer with a certain amount of experience. If so, then as shown above, there was no disclosure to any doctor or medical device specialist other than those who understood the disclosures were confidential. The surgical technicians and RN would not have had the level of skill in the art Medtronic's own expert, Dr. Lenke, said was needed to understand the inventions. Nonetheless, the degree of confidentiality is but one factor in determining public use, yet this factor weighs heavily in favor of Dr. Barry.

iv. No sale or commercial use for on sale bar or public use

There clearly was no sale of the invention under the U.C.C. or other contract for an on-sale bar. Dr. Barry was paid to do surgeries, not for his method and apparatus, which he kept under his control, and which were never implanted in the patient. There was no commercial use because the evolution and testing of the invention was not to test the market. In *TP Products*, a dental practitioner, testing a new retainer, charged two of its patients their normal fee for treatment of orthodontic problems, including hardware. 724 F.2d at 972. Dr. Barry charged the same fee regardless of method or tools.

Sinskey v. Pharmacia Ophthalmics, Inc., 982 F. 2d 494 (Fed. Cir. 1992) is not applicable. There, the surgeon testified in his deposition that no testing was required for him to know what he was doing or whether the device worked. He billed his regular fee, the patient was charged for the implanted inventive device, and there was no follow up. To the contrary, as shown by the IMAST slides and Dr. Barry's testimony, there was follow up in this case. As shown by the IMAST slides, Figure 1 of the patents, and Dr. Barry's declaration, the invention continued to develop from its original iteration to the inventions as claimed over time. Further, in *Sinesky*, the primary holding of the case was an unsupported change in testimony from a prior deposition to a declaration in opposition to summary judgment. Here, no such change has occurred and the testimony is an elaboration on facts relevant to a defense Medtronic raised—and on which it bears the burden—and is corroborated by documents and other witnesses.

Medtronic cannot litigate by invective or blurring over the law. Its request for lease to file a motion under 102(b) should be denied.

Respectfully submitted,

/s/ James Reed, Jr.
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